

REMARKS

This Amendment is submitted in reply to the non-final Office Action dated May 28, 2009. No fee is due in connection with this Amendment. The Director is authorized to charge any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-706 on the account statement.

Claims 1-12 and 14-15 are pending in this application. Claims 6-8, 12 and 14-15 were previously withdrawn from consideration, and Claim 13 was previously canceled without prejudice or disclaimer. In the Office Action, Claims 1-5 and 9-11 are objected to due to informalities. Claims 1-5 and 9-11 are rejected under 35 U.S.C. §112. Claims 1-2 are further rejected under 35 U.S.C. §102 or, alternatively, under 35 U.S.C. §103. Claims 3-5 and 9-11 are rejected under 35 U.S.C. §103. In response, Claims 1-5 and 9-11 have been amended. The amendments do not add new matter. At least in view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the objections and rejections should be withdrawn.

In the Office Action, Claims 1-5 and 9-11 are objected to due to informalities. See, Office Action, page 2, line 16. Specifically, the Patent Office asserts that Claims 1, 9 and 11 recite "natural lycopene concentrate" instead of "a natural lycopene concentrate," and Claims 2-5 similarly recite "Concentrate" instead of "The concentrate according to claim 1." See, Office Action, page 2, lines 17-21. In response, Applicants have amended Claims 1, 9 and 11 to recite "a natural lycopene concentrate" and Claims 2-5 to recite "The concentrate according to claim 1" in accordance with the Patent Office's suggestions. Thus Applicants respectfully submit that the objections to Claims 1-5 and 9-11 be withdrawn.

In the Office Action, Claims 1-5 and 9-11 are rejected under 35 U.S.C. §112, first paragraph, for failure to comply with the written description requirement. The Patent Office asserts that the present Specification fails to provide support for the limitation in Claims 1 and 9-11 of a natural lycopene concentrate which "contains no solvent" because a natural lycopene concentrate inherently contains water, which is a solvent. See, Office Action, page 3, lines 11-22. In response, Applicants have amended Claims 1 and 9-11 to clarify that the natural lycopene concentrate "contains no organic solvent." These amendments do not add new matter. The

amendments are supported in the Specification at, for example, page 1, paragraph 3, lines 4-7; paragraphs 4-5; paragraph 6, lines 5-10; paragraph 20, lines 6-9. Thus, Applicants respectfully submit that Claims 1-5 and 9-11 are fully supported by the present Specification.

Accordingly, Applicants respectfully request that the rejection of Claims 1-5 and 9-11 under 35 U.S.C. §112, first paragraph, be withdrawn.

In the Office Action, Claims 1-5 and 9-11 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Patent Office asserts that the term “natural” in Claims 1 and 9-11 is a relative term which is not defined by the claims or specification and whose scope could not be reasonably ascertained by one of ordinary skill in the art. See, Office Action, page 4, lines 10-14. In response, Applicants respectfully submit that the Specification describes a “natural” product as one which “has only been subjected to technological treatments which do not modify its native characteristics.” See, Specification, page 1, paragraph 7. The Specification further teaches that the lycopene concentrate is obtained “without using a solvent during the process in order to preserve the natural nature of the product.” See, Specification, page 1, paragraph 20, lines 4-7. Thus, Applicants respectfully submit that the scope of the term “natural” in Claims 1-5 and 9-11 is sufficiently clear to one of ordinary skill in the art.

The Patent Office further asserts that the phrases “the use of a solvent” in Claims 1 and 9-11 and “the ageing” in Claims 9-10 lack sufficient antecedent basis. See, Office Action, page 4, lines 17-20; page 5, lines 1-3. In response, Applicants have amended Claims 1 and 9-11 to recite that the lycopene concentrate is extracted from a lycopene-containing material without “using” a solvent. Applicants have also amended Claims 9-10 to recite a composition which slows “ageing” of the skin. These amendments do not add new matter. The amendments are fully supported in the Specification at, for example, page 1, paragraph 20, lines 6-9; page 2, paragraphs 43 and 46. Thus, Applicants respectfully submit that Claims 1 and 9-11 have sufficient antecedent basis.

Accordingly, Applicants respectfully request that the rejection of Claims 1-5 and 9-11 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 1-2 are rejected under 35 U.S.C. §102(b) as being anticipated by or, alternatively, under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,871,574 to Kwaragi et al. (“Kwaragi”). For at least the reasons set forth below,

Applicants respectfully submit that *Kawaragi* fails to disclose each and every element of independent Claim 1 and Claim 2 that depends therefrom.

Currently amended independent Claim 1 recites, in part, a natural lycopene concentrate that contains no organic solvent and is water-soluble at room temperature comprising at least 1 mg of lycopene per g of the said concentrate, not more than 30% proteins, not more than 30% polysaccharides, not more than 10% organic acids, and at least 30% of lipid compounds, wherein the concentrate is isolated from fibers and other insoluble compounds by solid-liquid separation, and wherein the concentrate is extracted from a lycopene-containing material without using a solvent. Conventional lycopene concentrates are fat-soluble. See, Specification, page 1, paragraph 9, lines 1-3. However, by forming the lycopene in a complex with proteins and polysaccharides, the lycopene concentrate is water-soluble. See, Specification, page 2, paragraph 40. In contrast, Applicants respectfully submit that *Kawaragi* fails to disclose or suggest every element of the present claims.

For example, *Kawaragi* fails to disclose a lycopene concentrate that contains no organic solvent and comprises at least 1 mg of lycopene per g of the said concentrate (i.e., 0.1 wt %) as required, in part, by independent Claim 1. The Patent Office asserts that *Kawaragi* discloses a lycopene concentrate that contains no organic solvent and has a lycopene content of 12 mg %. See, Office Action, page 6, lines 29-31; page 4, lines 1-4. However, Applicants respectfully submit that the lycopene content in mg % merely represents (the absorbance at 480 nm)*20.16/(the weight of the specimen (g)). See, *Kawaragi*, column 6, lines 19-20. In fact, nowhere does *Kawaragi* disclose the weight percentage (mg/g) of lycopene in the mashed and centrifuged liquid, nor does the Patent Office cite support for a lycopene concentrate which contains at least 1 mg of lycopene per g of concentrate. See, *Kawaragi*, column 5, lines 66-67 (merely shows a lycopene content of 0.5-500 mg %); column 11, lines 15-46. Furthermore, even if the mg % can be considered a weight percentage such that the lycopene product contains at least 0.1 wt % lycopene, nowhere does *Kawaragi* teach or suggest that the lycopene may be extracted without using a solvent such that the lycopene concentrate contains no organic solvent.

Contrary to the Patent Office's assertion, *Kawaragi* teaches that the lycopene content (mg %) of all its examples is determined by cleaning the specimen with the organic solvent methanol and extracting the lycopene with the organic solvent benzene. See, *Kawaragi*, column 6, lines

10-20 ("Analysis of lycopene in the following Examples was made according to the method of [Handbook of Analysis, Tomato Products], in which the methanol-cleaned specimen is extracted with benzene, then absorbance of the extract is measured at 480 nm"). As such, Applicants respectfully submit that all of the lycopene products disclosed in *Kawaragi* contain a solvent (benzene). Therefore, *Kawaragi* fails to disclose a lycopene concentrate that contains no organic solvent and comprises at least 1 mg of lycopene per g of the said concentrate in accordance with the present claims.

Moreover, *Kawaragi* fails to disclose a natural lycopene concentrate that is water-soluble and comprises not more than 30% proteins, not more than 30% polysaccharides, not more than 10% organic acids, and at least 30% of lipid compounds as required, in part, by independent Claim 1. The Patent Office admits that *Kawaragi* fails to explicitly disclose the claimed amounts of proteins, polysaccharides, organic acids and lipid compounds but nevertheless asserts that the lycopene concentrates would inherently contain the claimed amount of each component merely because *Kawaragi* starts with the same plant material tomato and uses no solvent to obtain its concentrate. See, Office Action, page 7, lines 4-10. However, as discussed previously, *Kawaragi* expressly teaches the use of a solvent to extract lycopene and determine the lycopene content in the products, which is directly contrary to the present claims. See, *Kawaragi*, column 6, lines 10-20. *Kawaragi* also teaches that its entire goal is to reduce the amount of lipid compounds such as carotenoids and thereby improve the pigment of the tomato by adding an organic solvent to a lycopene retentate and purifying the product. See, *Kawaragi*, column 1, lines 46-67; column 2, lines 1-25; column 5, lines 8-21. In addition, nowhere does *Kawaragi* disclose that its product is water-soluble. Instead, *Kawaragi* merely states that its tomato pigment maintains water dispersibility of the lycopene-containing tomato particles. See, *Kawaragi*, column 1, lines 60-62. Applicants respectfully submit that one of ordinary skill in the art would understand that water dispersibility is distinguishable from water solubility.

Furthermore, contrary to the Patent Office's assertion, *Kawaragi* uses a different process to obtain its product and thus results in a different product. *Kawaragi* discloses obtaining its tomato pigment by first washing and mashing tomato fruit and squeezing it through a screen to obtain a tomato juice. See, *Kawaragi*, column 11, lines 14-19. The tomato juice is then subjected to a centrifuge and microfiltered to obtain a highly concentrated lycopene solution as

the membrane retentate. See, *Kawaragi*, column 11, lines 20-28. *Kawaragi* then teaches adding food additive ethanol (*i.e.*, a solvent) to the product and separating the sediment from the ethanol phase to obtain the desired bright-red tomato pigment. See, *Kawaragi*, column 11, lines 39-47. In contrast, the present product is obtained by mixing tomato puree with water and adding a base to raise the pH to approximately 7. See, Specification, page 2, paragraph 52. The solution is heated, filtered, cooled and acidified. See, Specification, page 2, paragraph 53; page 3, paragraphs 54-55. The resulting solution is centrifuged, and the recovered supernatant is adjusted to a pH of approximately 7. See, Specification, page 3, paragraphs 56-59. As such, the claimed product is obtained without the use of a solvent in order to preserve the natural qualities of the lycopene. See, Specification, page 1, paragraph 20. Furthermore, the lycopene is water-soluble because it forms a complex with proteins and polysaccharides. See, Specification, page 2, paragraph 40. Applicants thus respectfully submit that *Kawaragi* does not inherently disclose the claimed product because it uses a different process to obtain its tomato pigment.

Kawaragi also fails to render the claimed lycopene concentrate obvious. The present claims recite a natural lycopene concentrate that contains no organic solvent and comprises not more than 30% proteins, not more than 30% polysaccharides, not more than 10% organic acids, and at least 30% of lipid compounds. In contrast, as discussed previously, *Kawaragi* is entirely directed to improving the pigment of a tomato by adding an organic solvent to a lycopene retentate. See, *Kawaragi*, column 1, lines 46-67; column 2, lines 1-25; column 5, lines 8-21. Therefore, one of ordinary skill in the art would have no reason to modify the product of *Kawaragi* to obtain a lycopene concentrate that contains no organic solvent because *Kawaragi* teaches improving the quality of its product by adding an organic solvent. Furthermore, nowhere does *Kawaragi* disclose or suggest that increasing the quantity of lipids or reducing the amount of polysaccharides results in an increased bioavailability of the lycopene. As such, *Kawaragi* fails to suggest the claimed amounts of polysaccharides or lipid compounds to one of ordinary skill in the art.

Accordingly, Applicants respectfully request that the rejection of Claims 1-2 under 35 U.S.C. §102(b) or, alternatively, under 35 U.S.C. §103(a) to *Kawaragi* be withdrawn.

In the Office Action, Claims 1-5 and 9-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Kawaragi* in view of "Vitamin C content of thirty-six varieties of tomatoes," FASEB Journal, Vol. 7, No. 3-4 (1993) to Hamm et al. ("*Hamm*") and further in view of U.S. Patent Publication No. 2003/0027772 A1 to Breton et al. ("*Breton*"). Applicants respectfully submit that, even if combinable, the cited references fail to disclose or suggest each and every element of Claims 1-5 and 9-11.

As discussed previously, *Kawaragi* fails to disclose or suggest a lycopene concentrate that: (1) contains no organic solvent and comprises at least 1 mg of lycopene per g of the said concentrate; and (2) is water-soluble and comprises not more than 30% proteins, not more than 30% polysaccharides, not more than 10% organic acids, and at least 30% of lipid compounds as required, in part, by independent Claim 1 from which Claims 2-5 depend, as well as independent Claims 9-11. The Patent Office relies on *Hamm* merely as support for a tomato containing vitamin C and *Breton* merely for the disclosure incorporating the claimed amount of lycopene into a dietary supplement. See, Office Action, page 8, lines 16-22; page 9, lines 1-10. Thus, Applicants respectfully submit that, even if properly combinable, *Hamm* and *Breton* fail to remedy the deficiencies of *Kawaragi* with respect to Claims 1-5 and 9-11.

Accordingly, Applicants respectfully request that the rejection of Claims 1-5 and 9-11 under 35 U.S.C. §103(a) to *Kawaragi*, *Hamm* and *Breton* be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly request an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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